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(54) **INDEXING CELL DELIVERY CATHETER**

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(52) **U.S. Cl.** **604/264**

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604/158-180, 43

See application file for complete search history.

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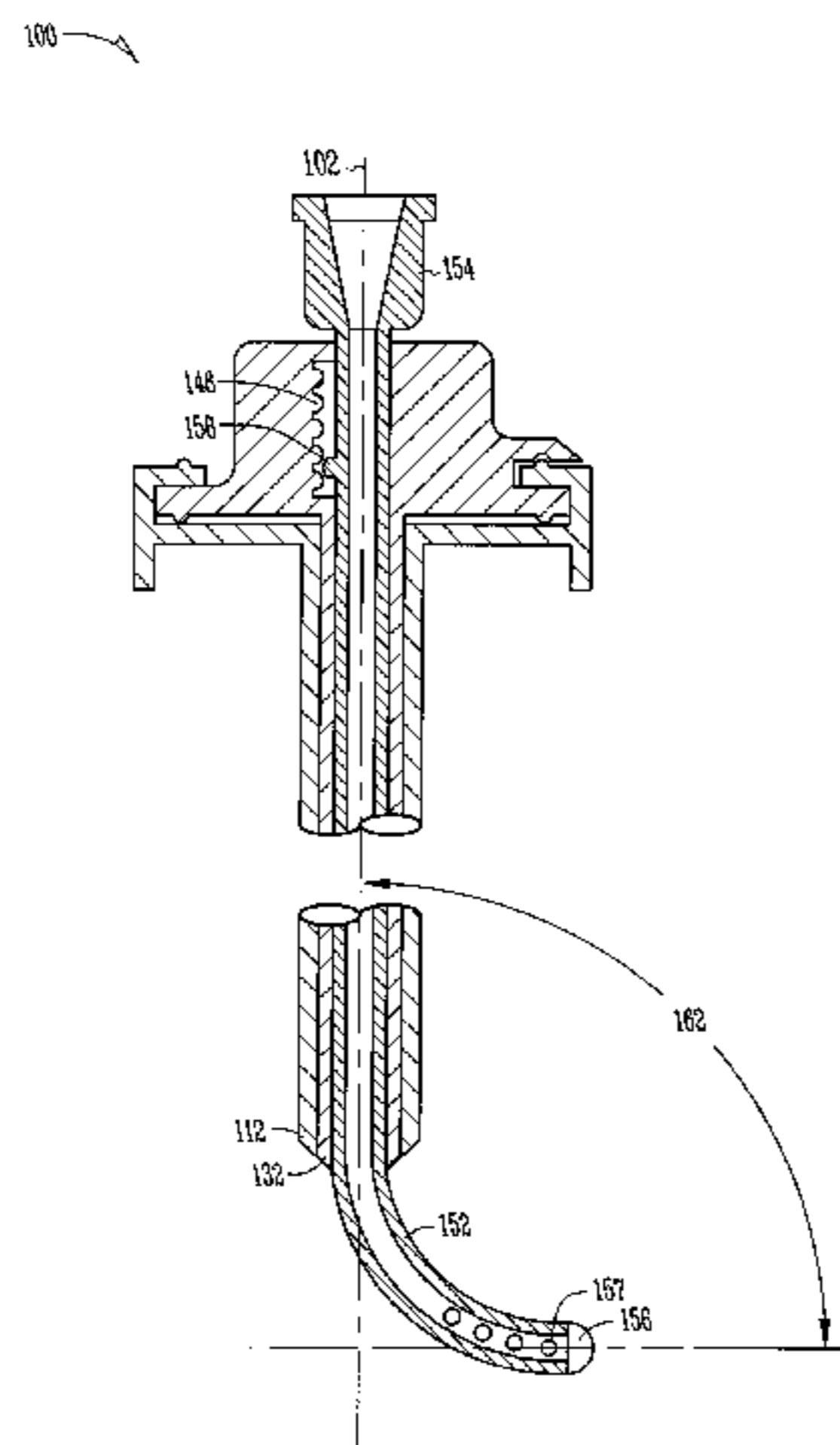
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(57) **ABSTRACT**

An insertion device and method of using and manufacturing an insertion device is shown, wherein the insertion device is capable of distributing a media over a large distribution volume inside a patient while reducing the amount of tissue disturbed by the procedure. Also shown is a computer-readable medium with instructions stored thereon, the instructions when executed operable to cause generation of a set of data for use with an insertion device. An insertion device and methods are shown that allows a series of iterations to be performed within a single insertion procedure that distributes media, such as cells for cell therapy, over a large volume.

21 Claims, 12 Drawing Sheets



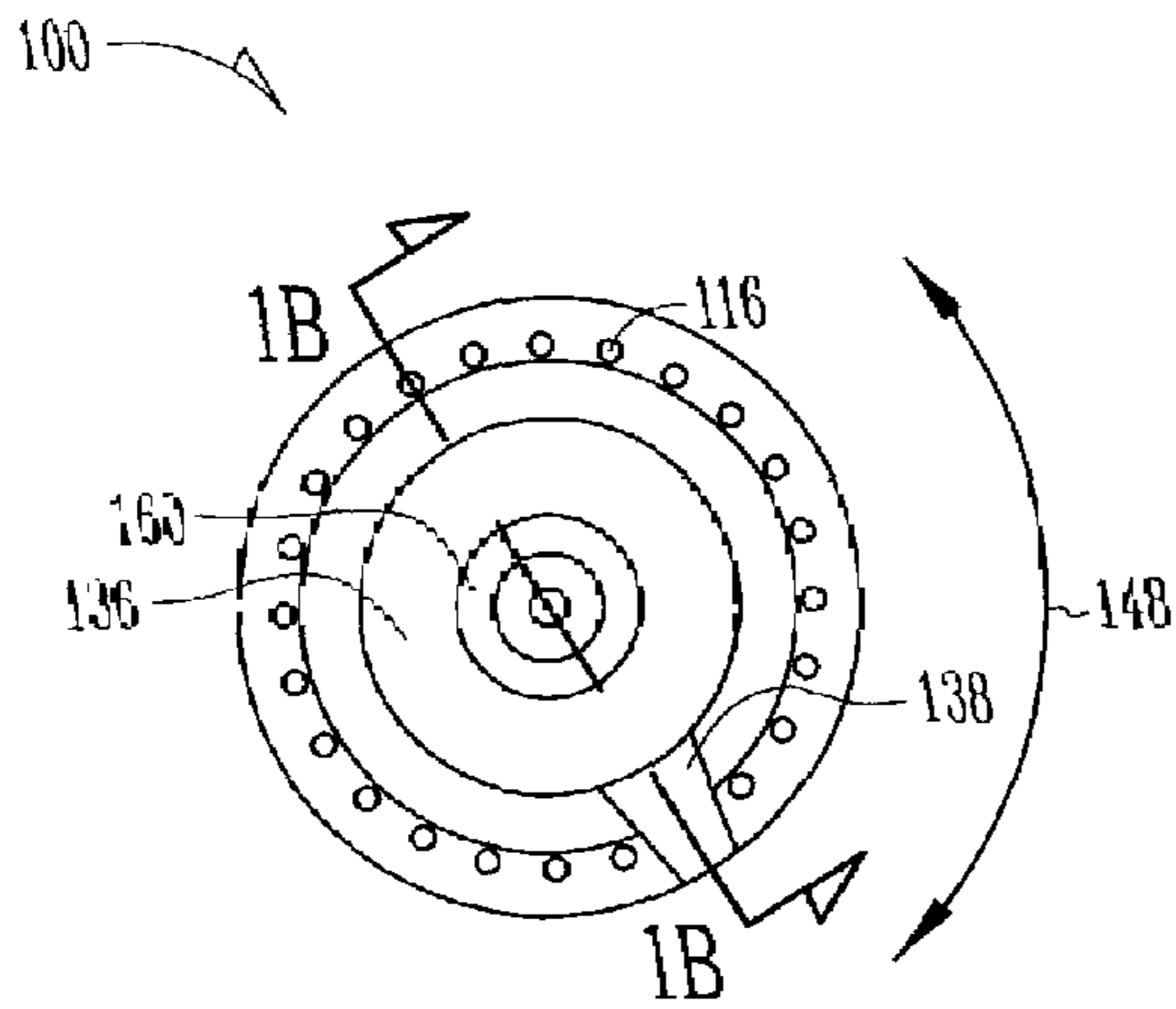


Fig. 1A

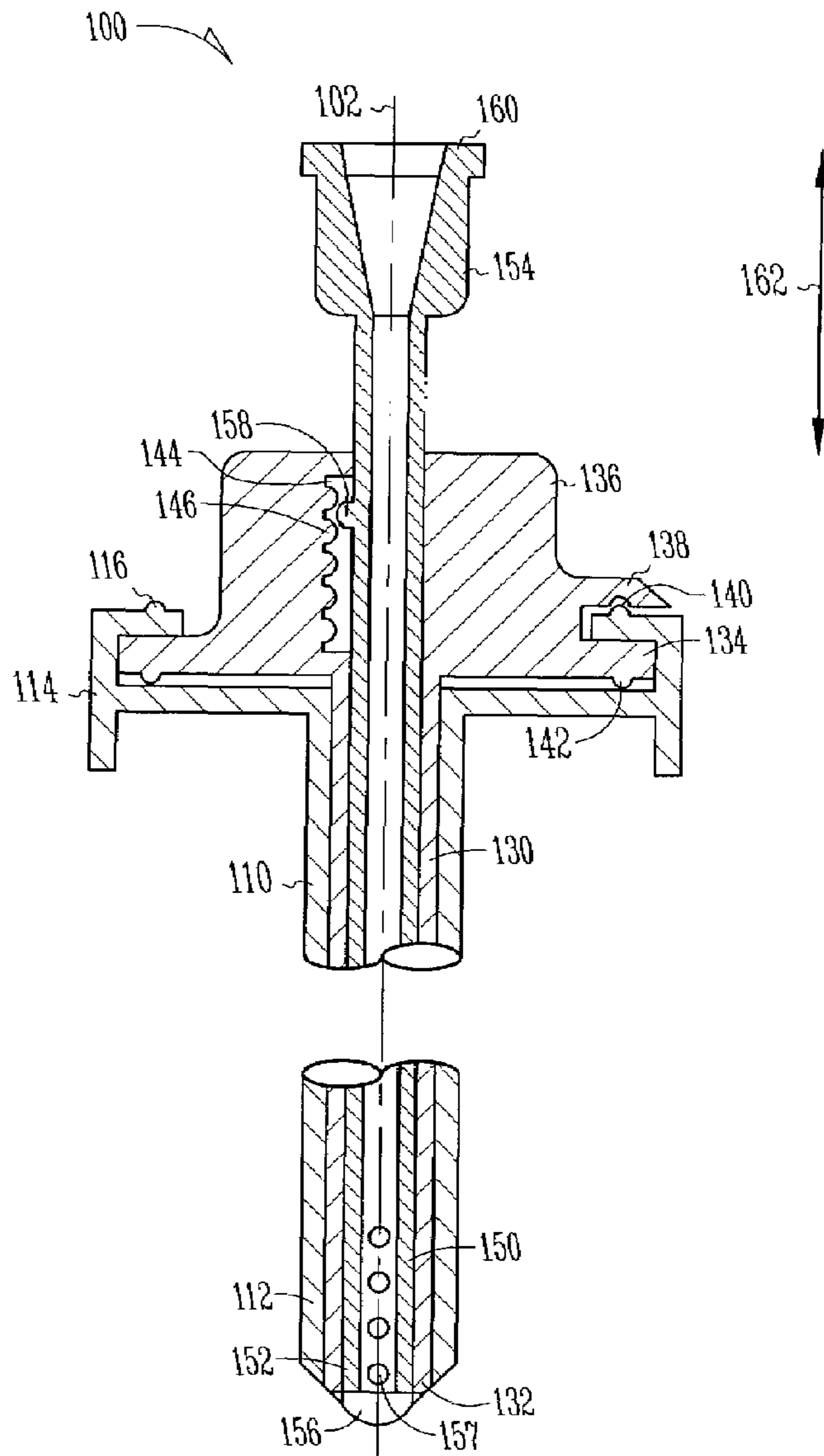


Fig. 1B

100

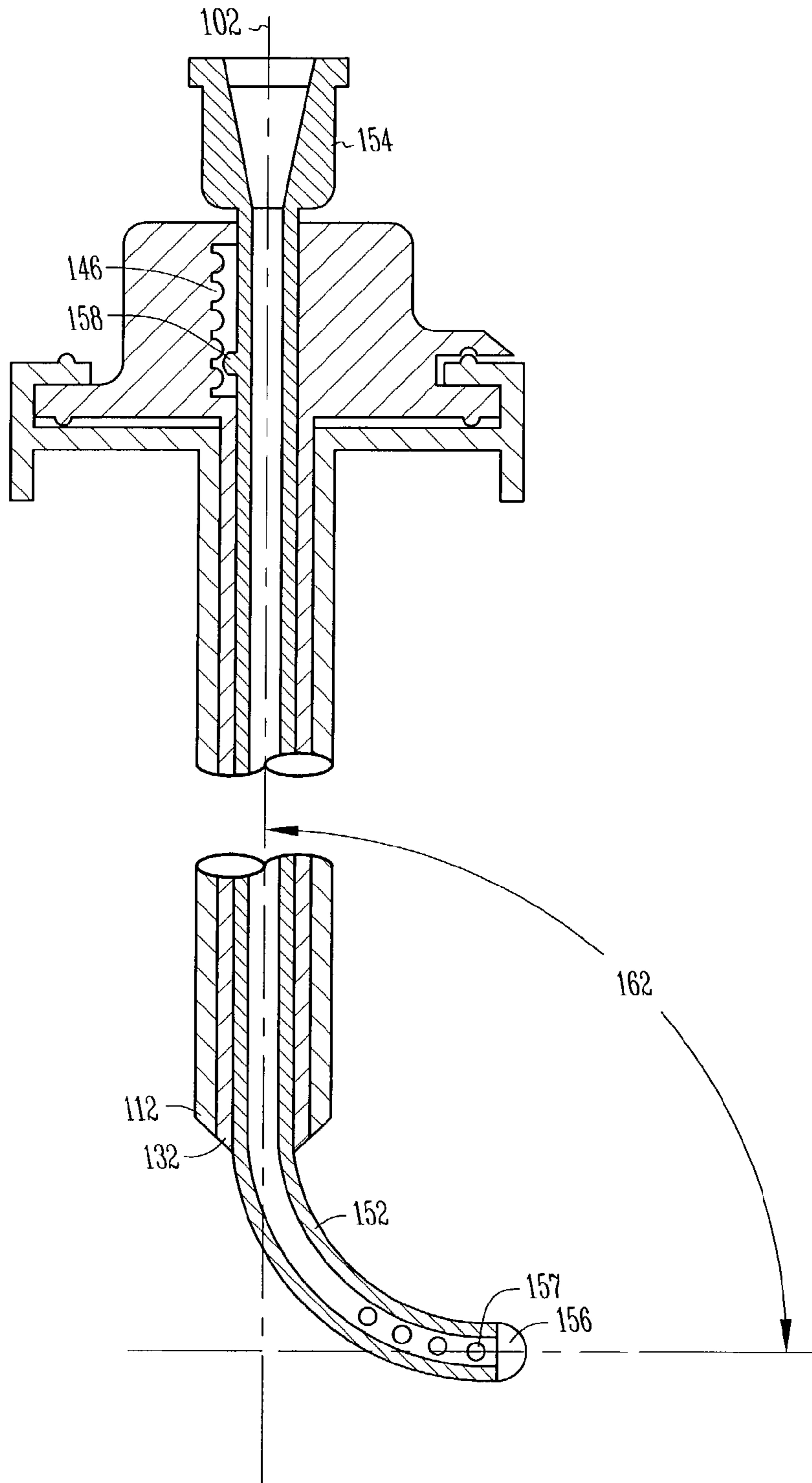


Fig. 1C

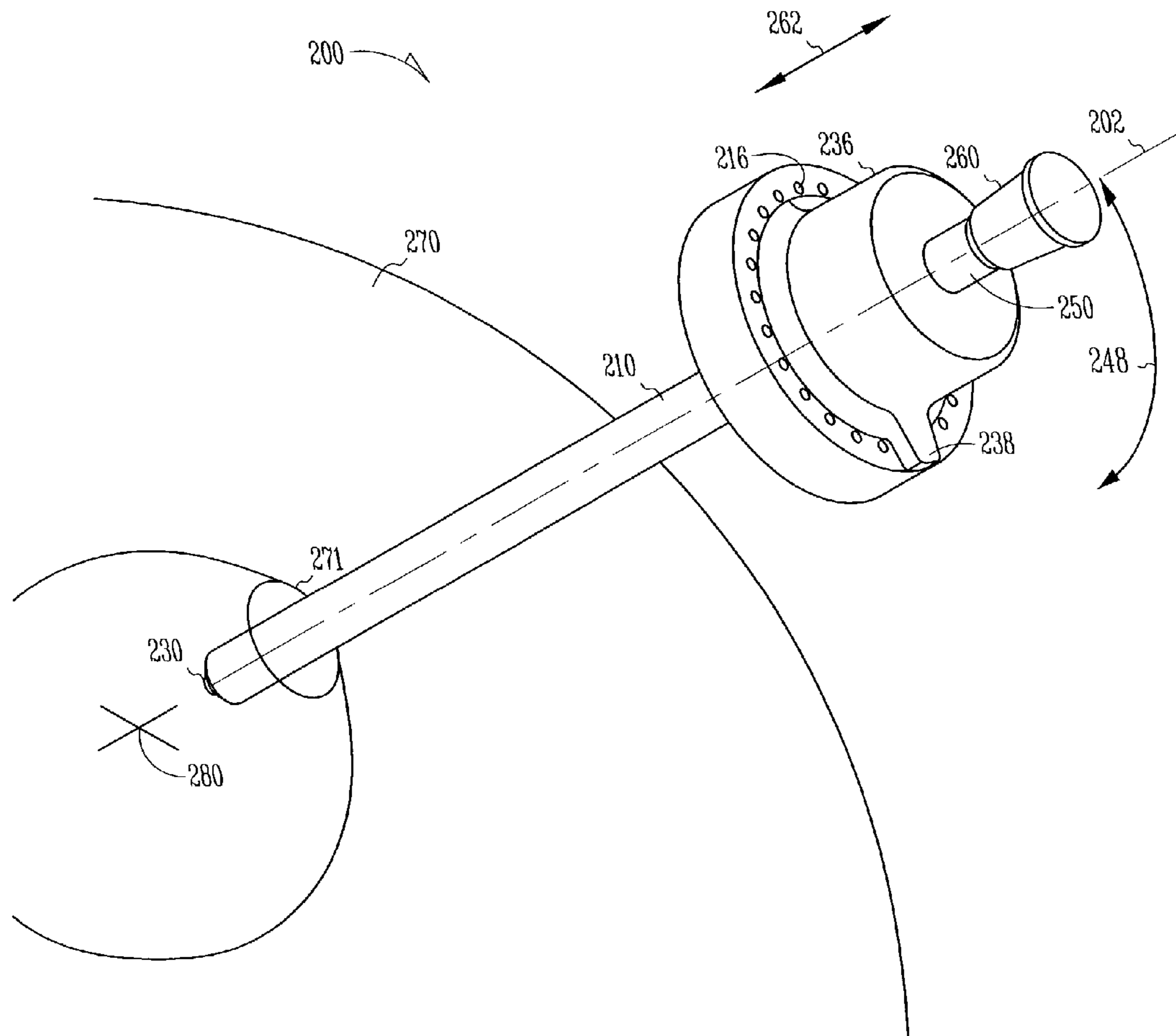


Fig.2A

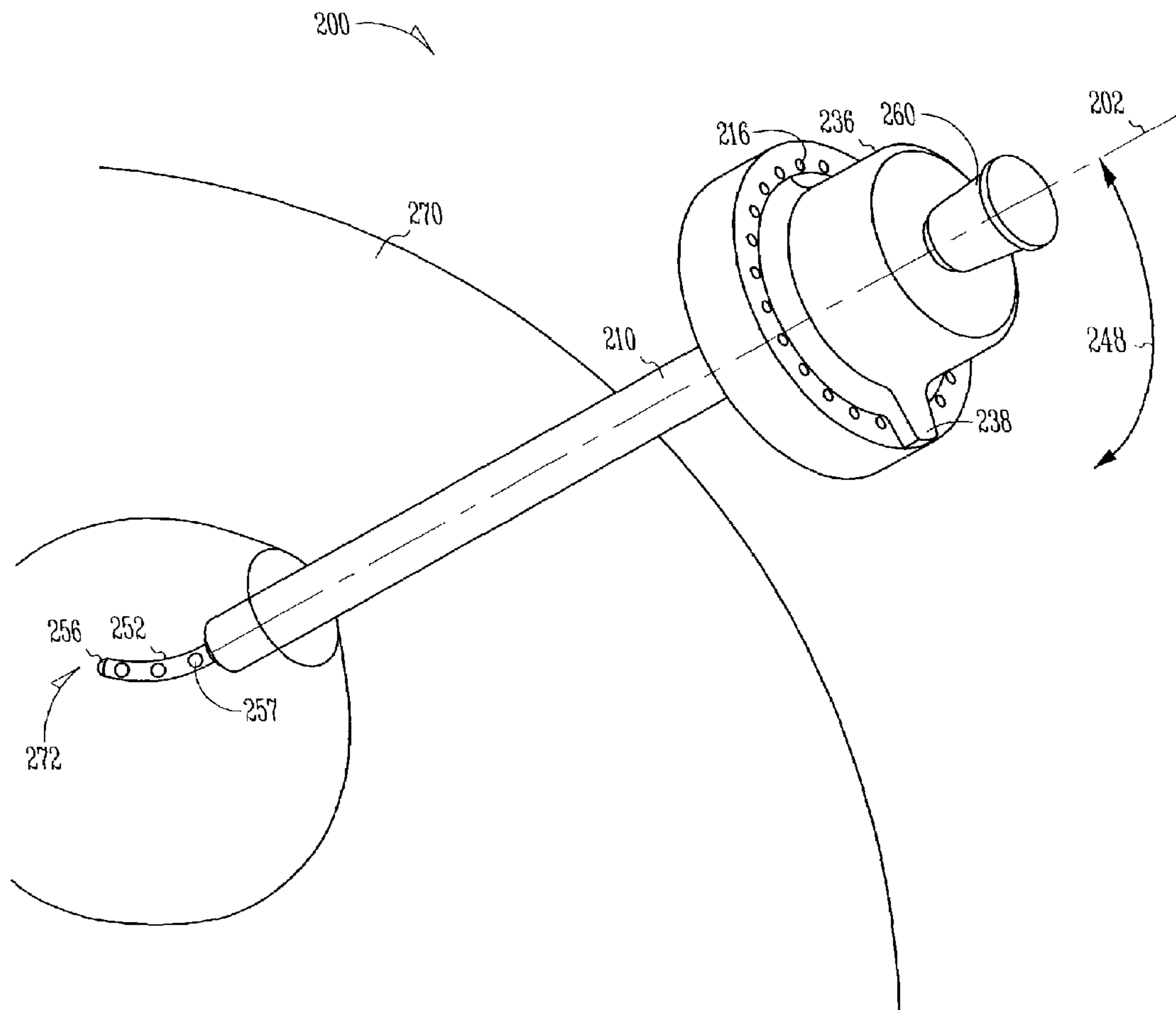


Fig.2B

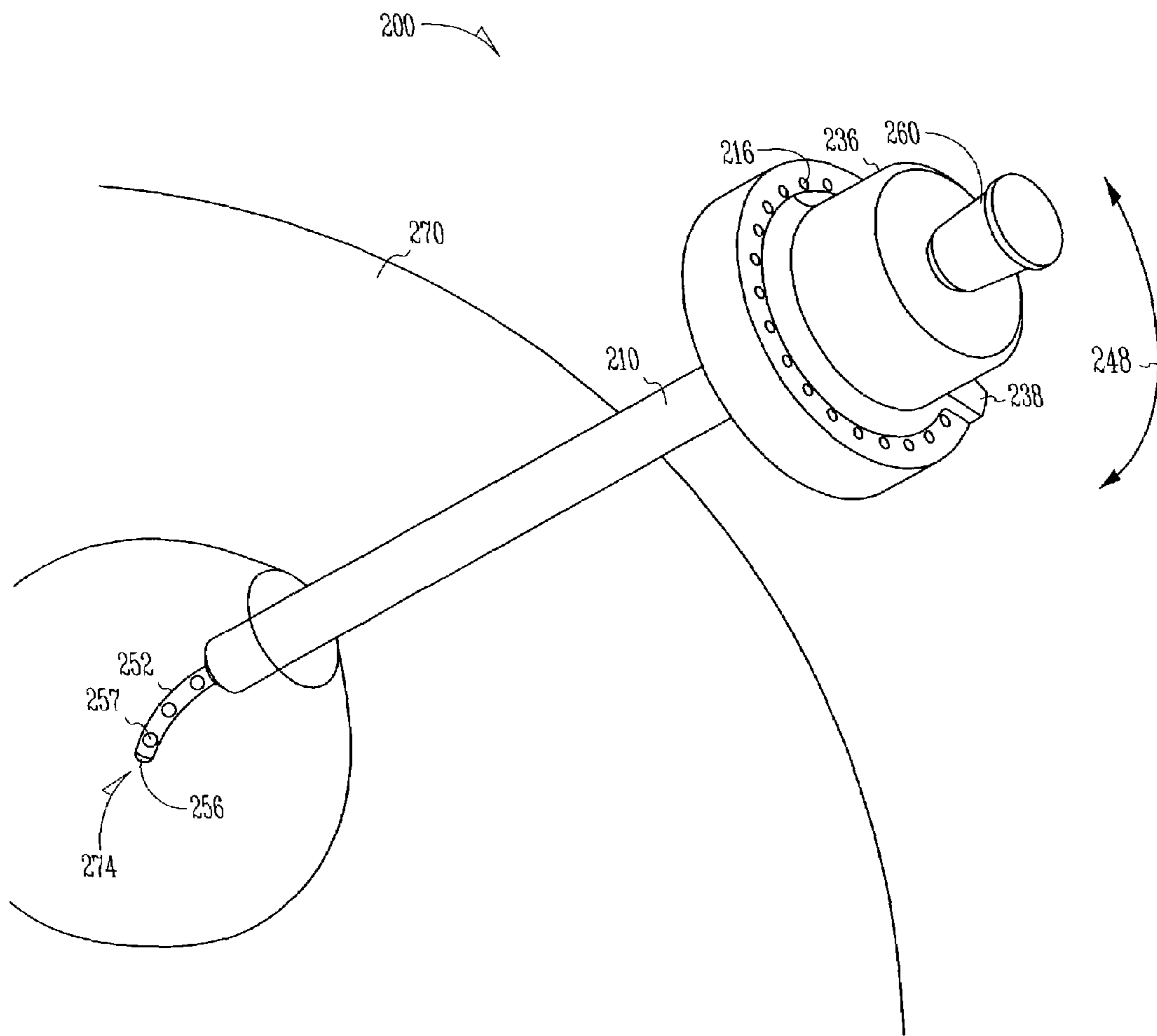


Fig.2C

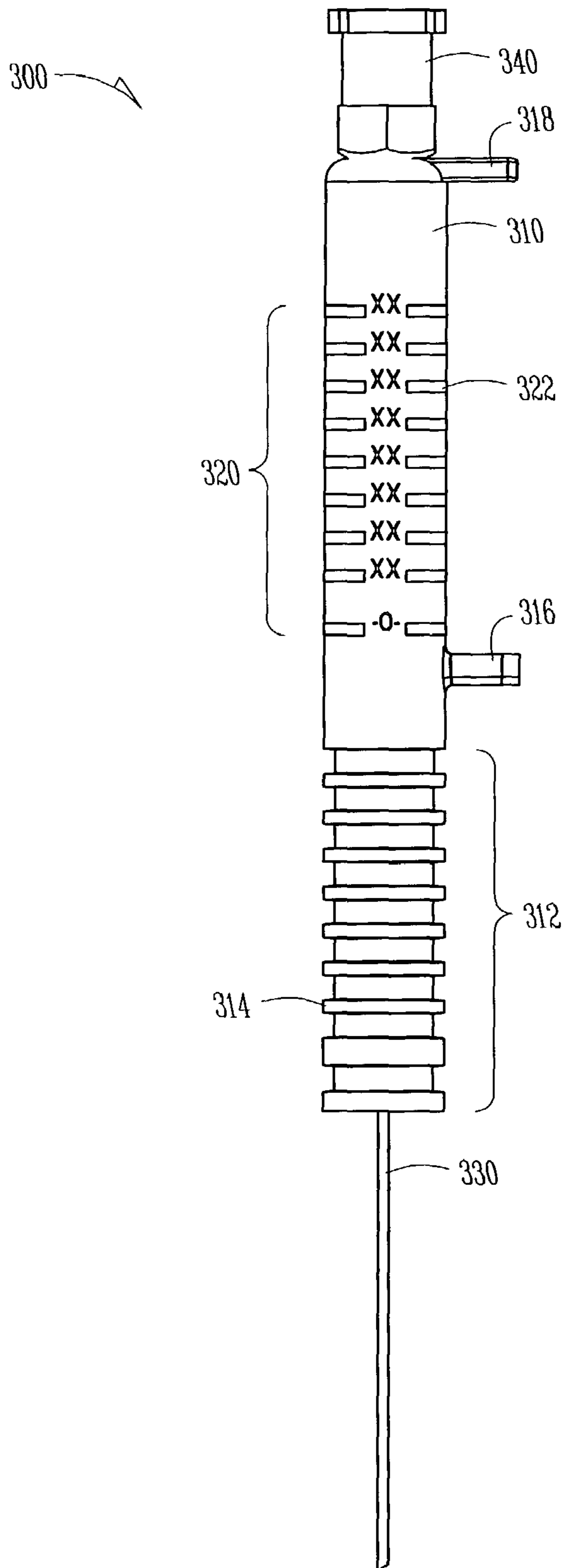


Fig.3

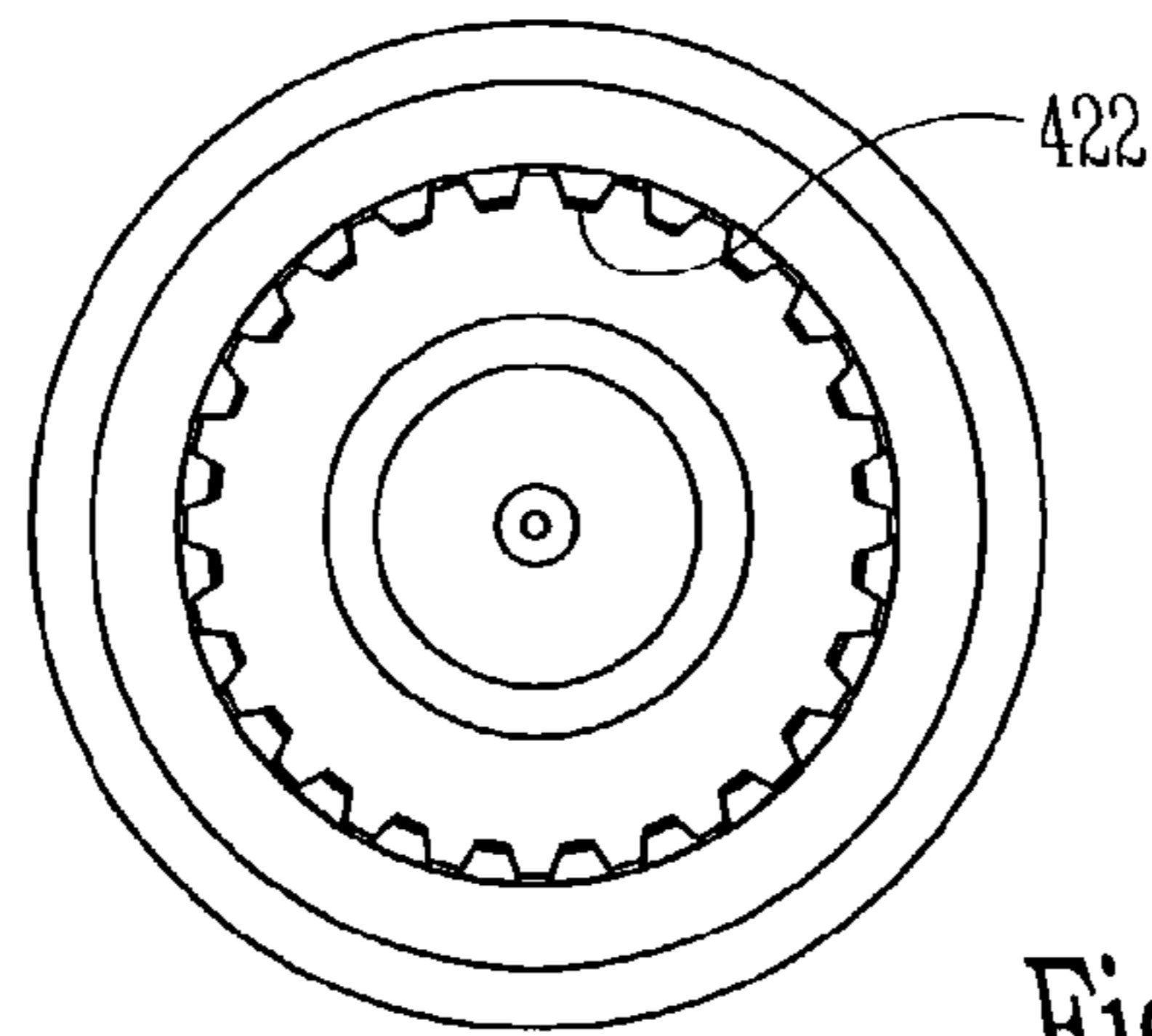


Fig. 4B

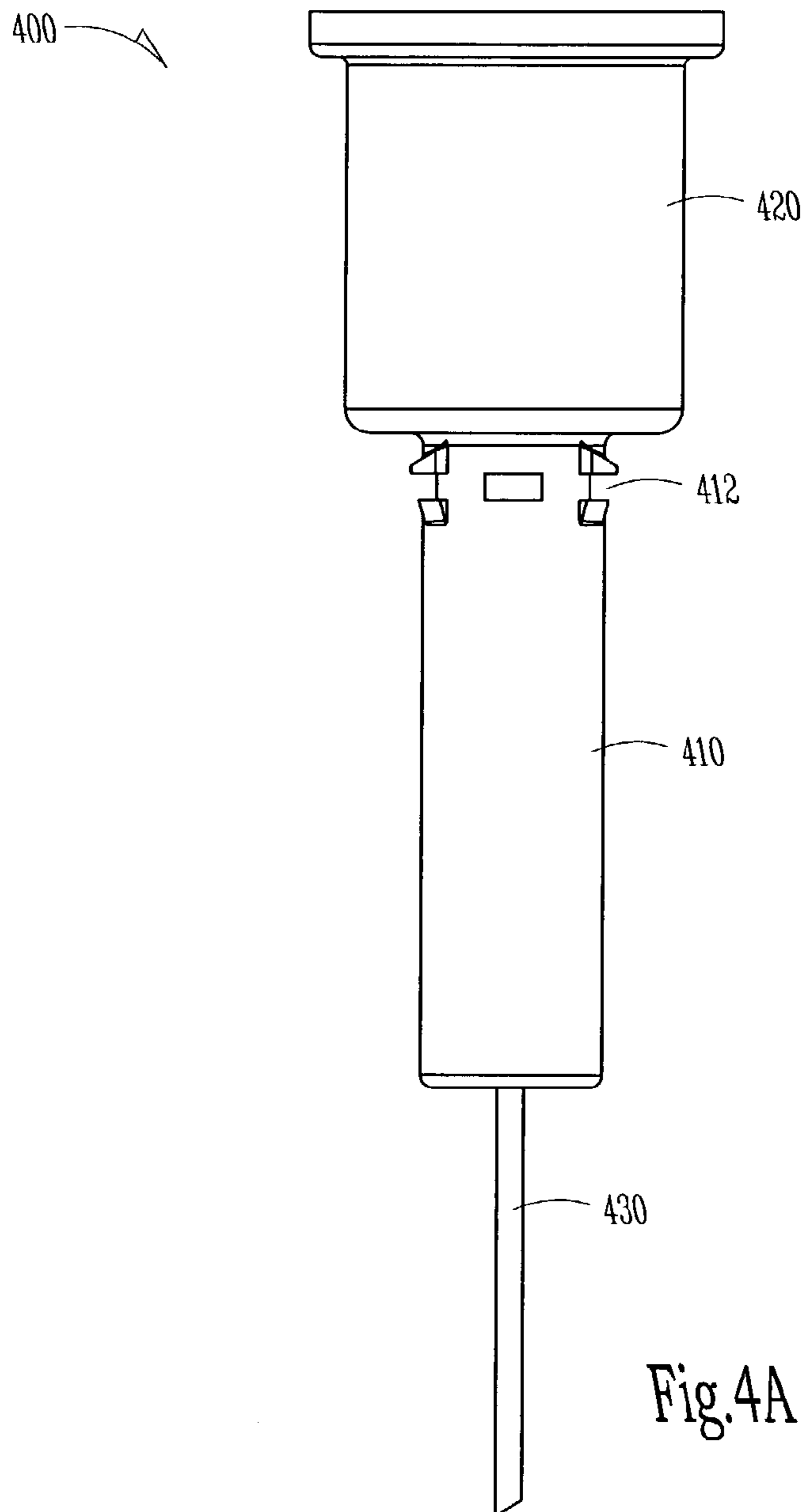
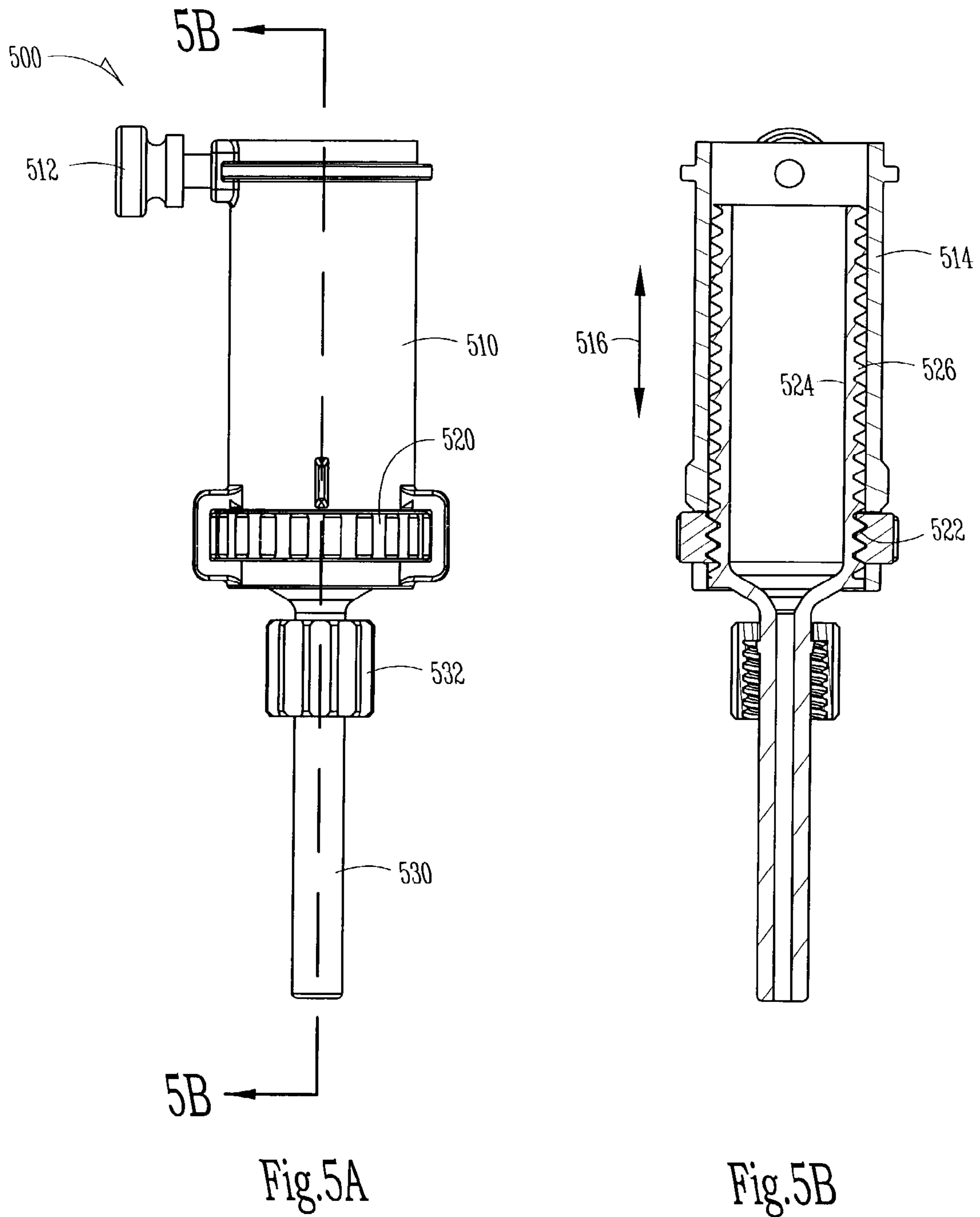
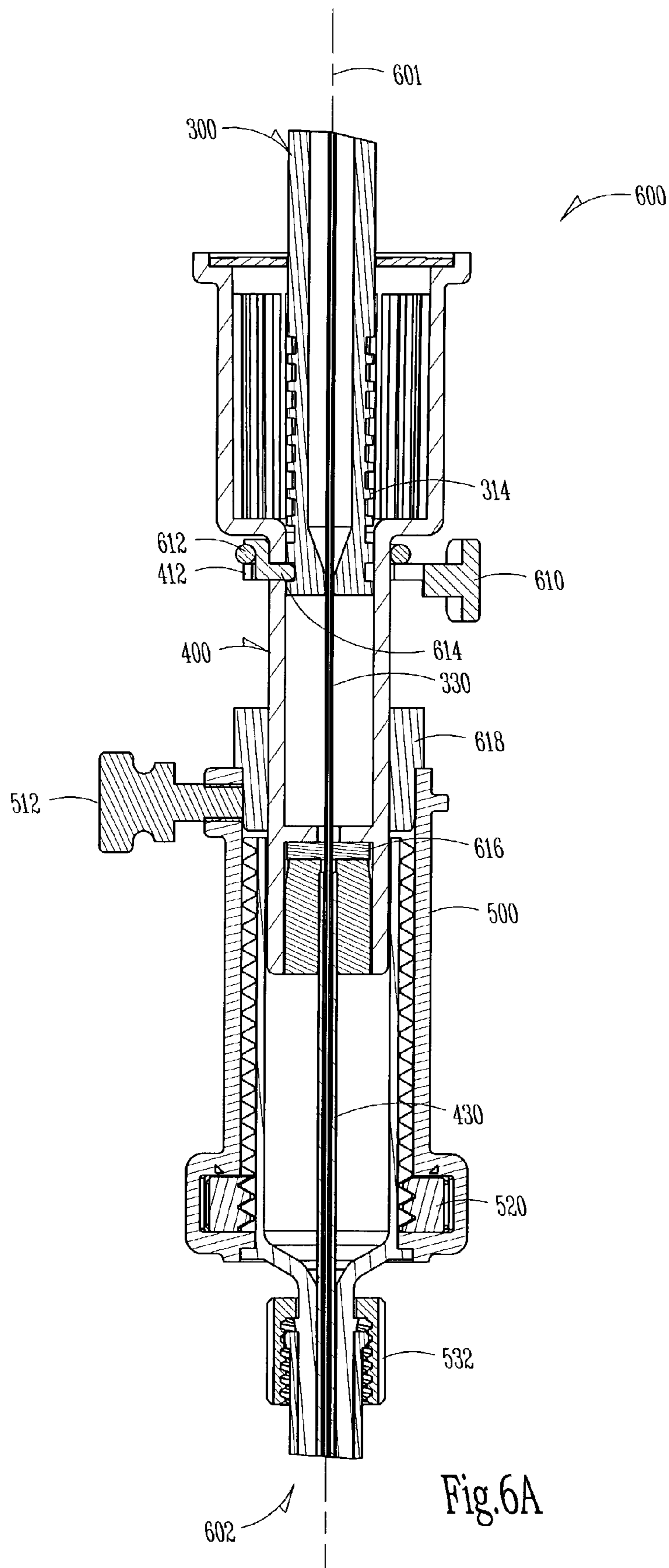
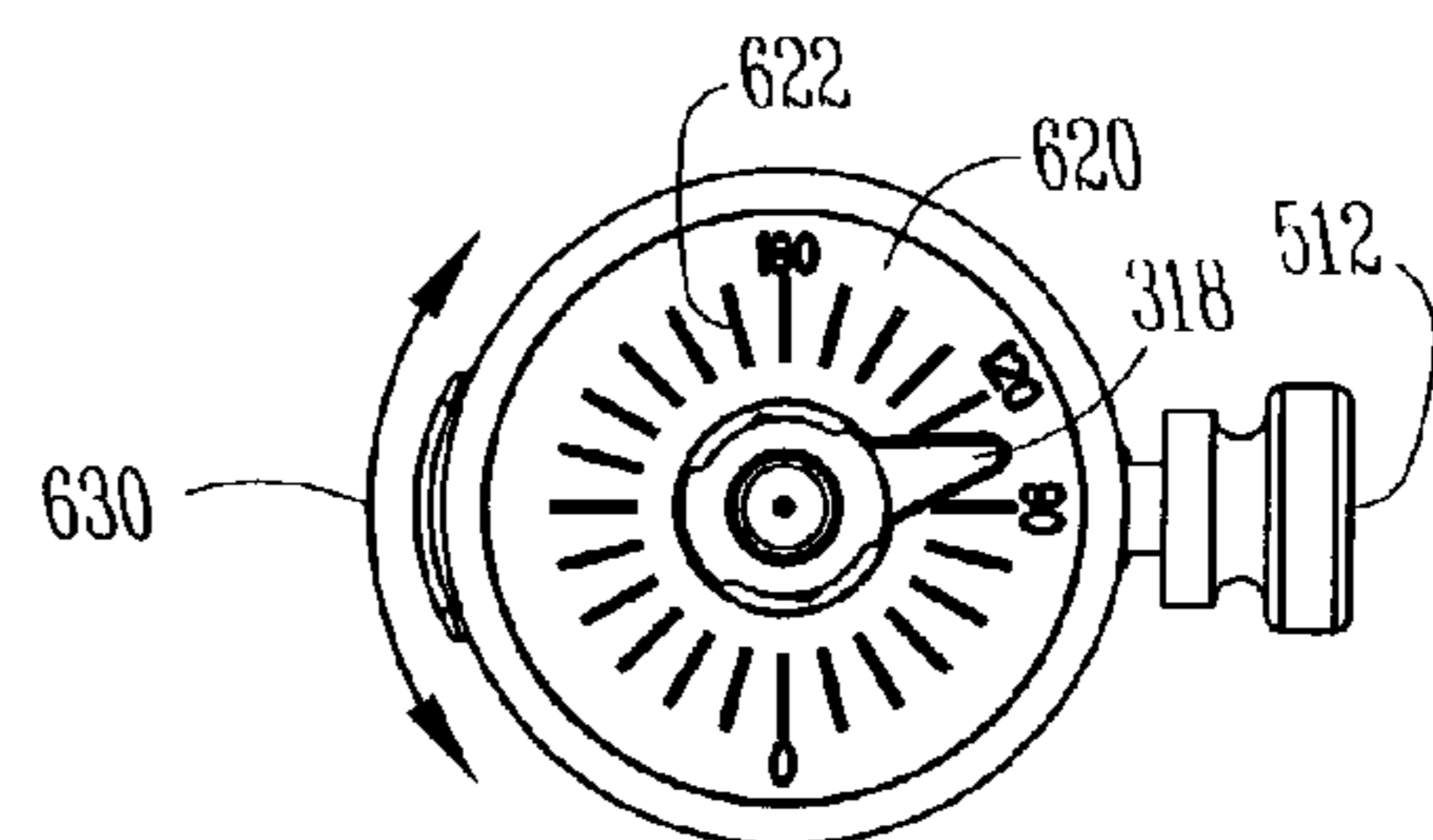
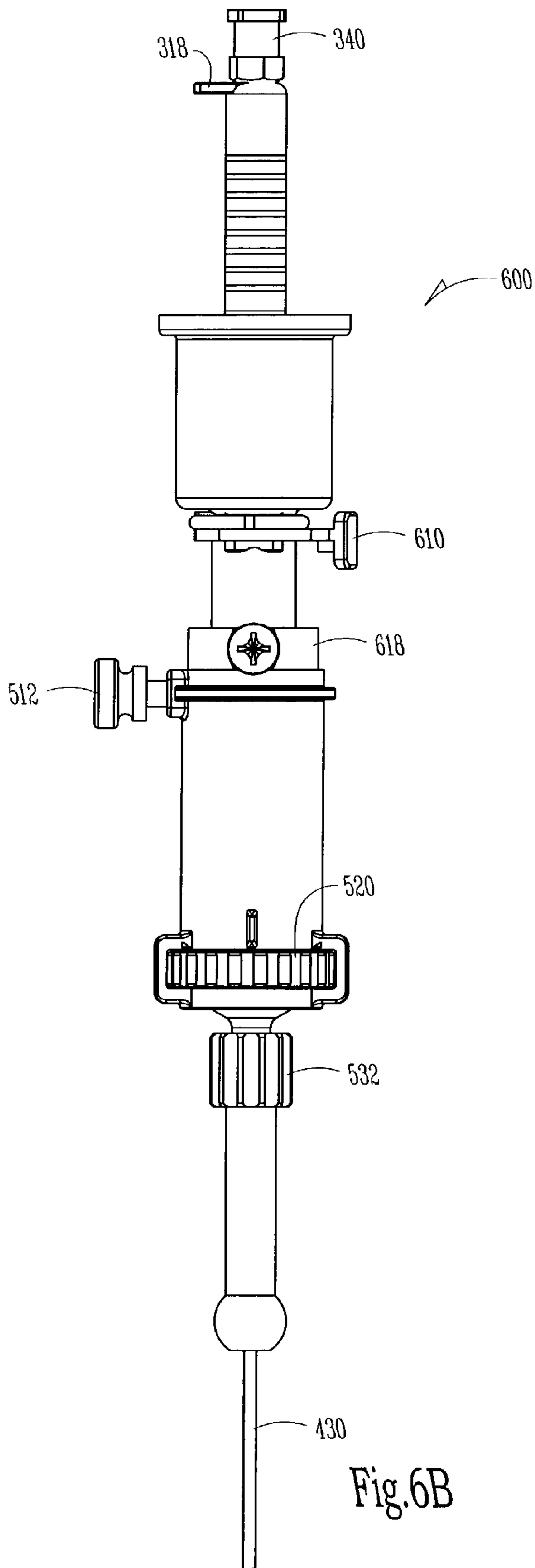


Fig. 4A







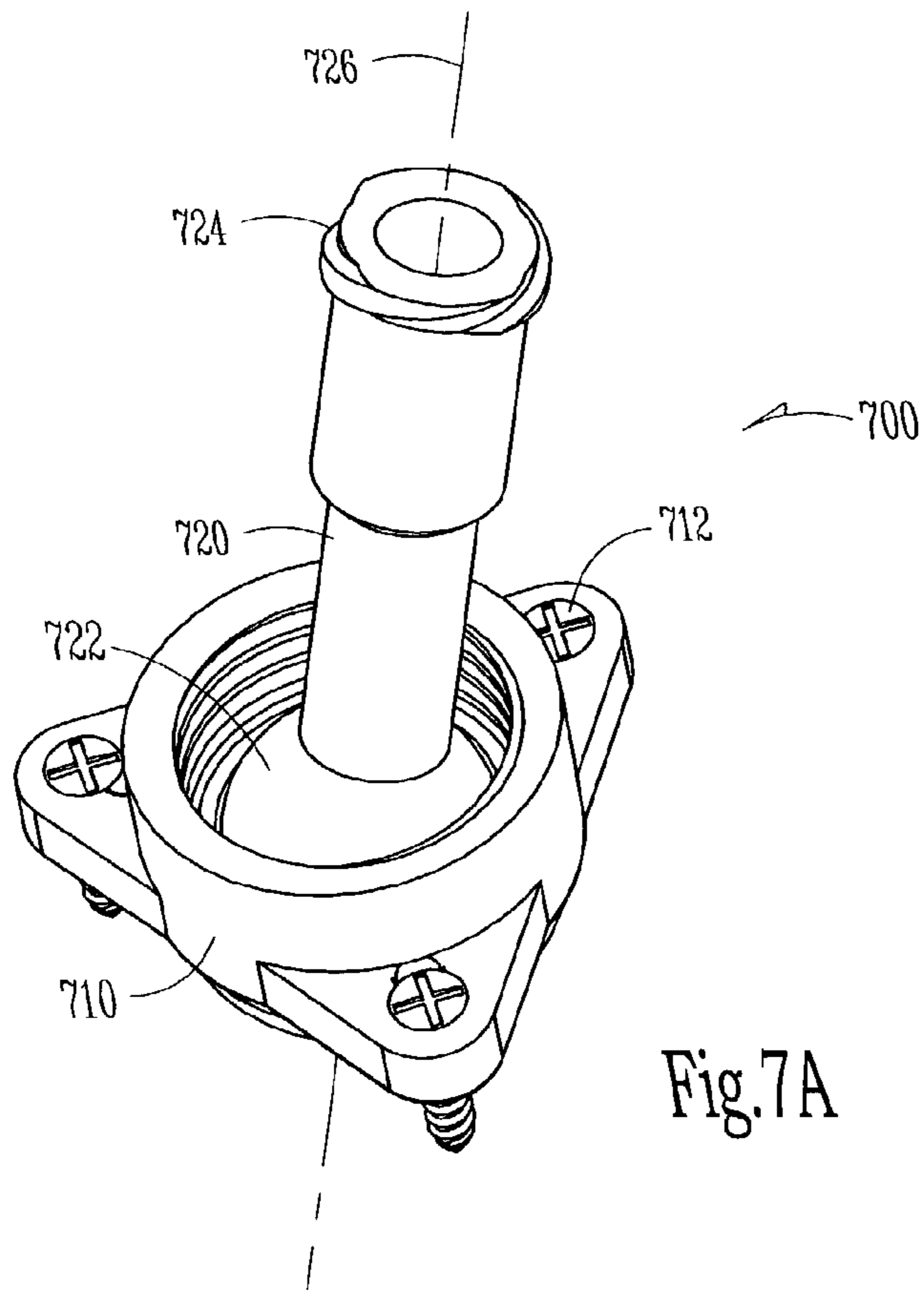


Fig. 7A

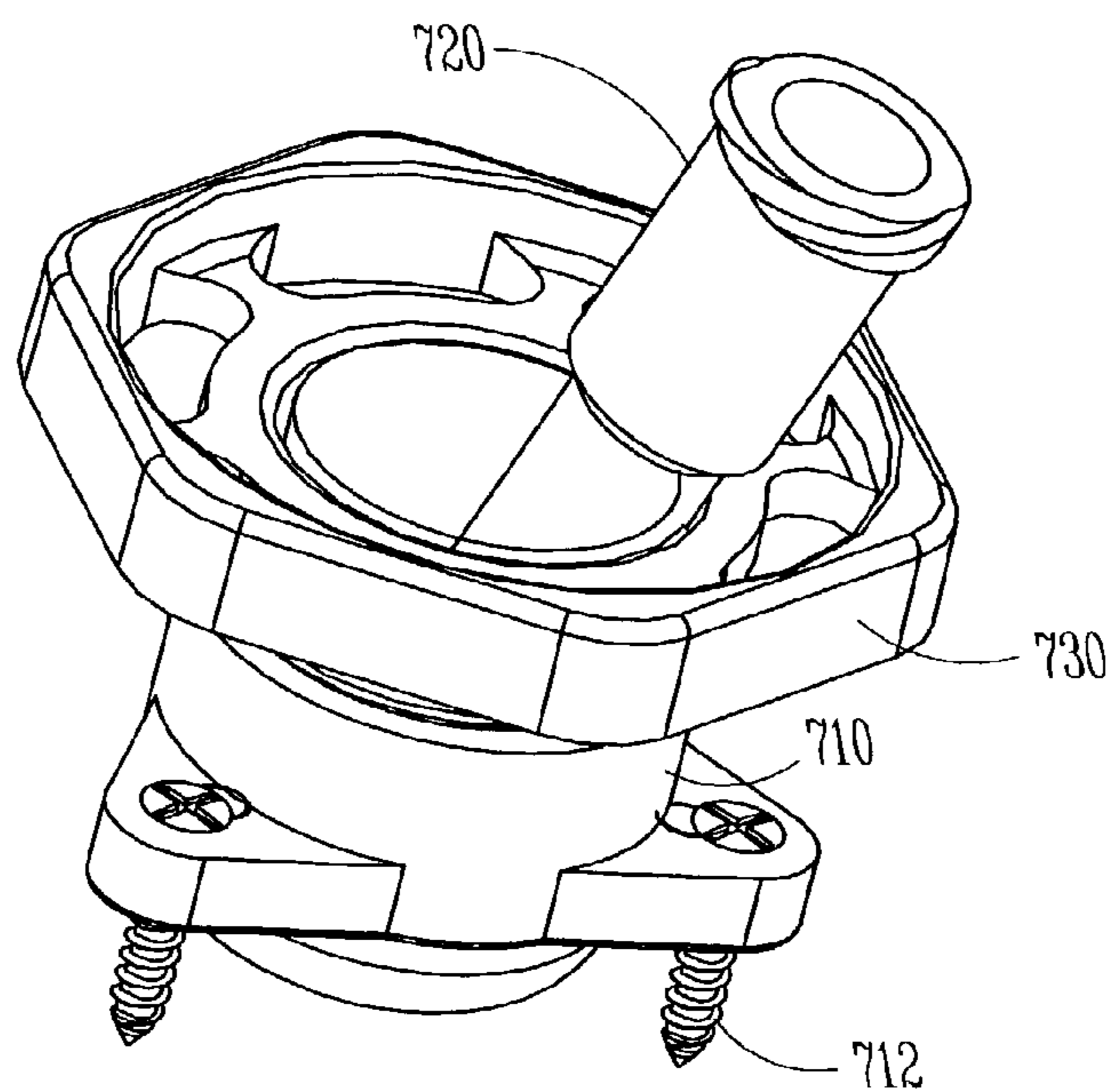


Fig. 7B

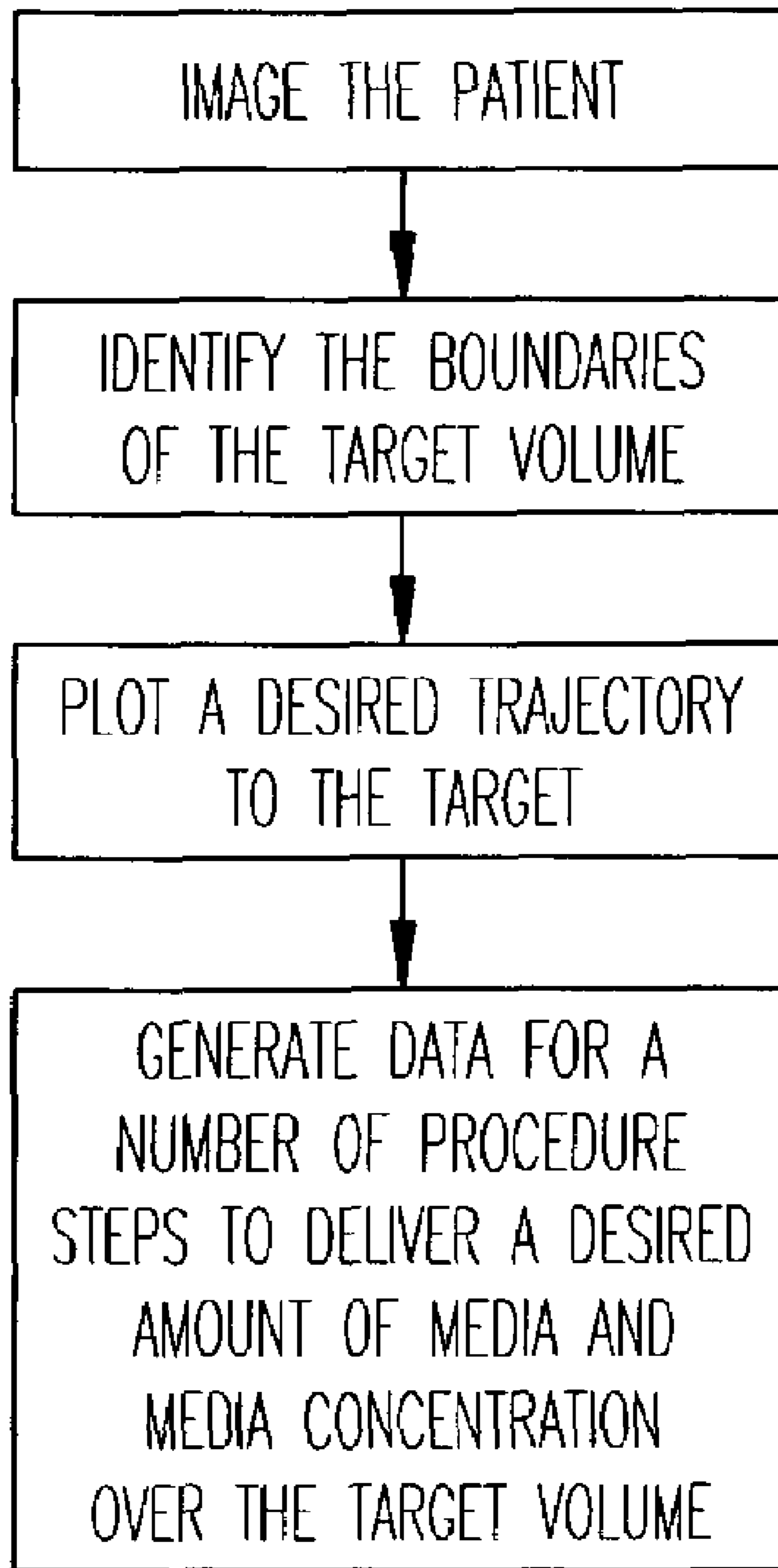


Fig.8

INDEXING CELL DELIVERY CATHETER

BACKGROUND

1. Field of the Invention

This invention relates to medical devices. Specifically, but not by way of limitation, this invention relates to medical devices for introduction of a media such as cells into a body cavity, such as within the human brain.

2. Background

In this document, the medical device that is described is inserted within a body cavity. While the insertion procedure could be directed at any of several locations within a patient, for the discussion in this document, a neurosurgical procedure will be used as an example. Assisting devices may also be used in combination with the present insertion device in a neurosurgical procedure. Such devices may include, but are not limited to, a stereotactic headframe, a trajectory guide, electronic tissue imaging equipment, and frameless reference systems.

A common surgical technique inserts a medical device into a patient to a targeted area through a small opening that is surgically opened in the patient. Inserting a device to the targeted area of the patient and disturbing as little tissue as possible is a high priority. Small openings are desirable because they are less invasive and less traumatic to the patient. A catheter is a broad category of medical devices that can be inserted into a patient through small openings. The term catheter could include several configurations of devices. In one basic form, a catheter includes a hollow tube, or passage to deliver a media such as a drug or other treatment media to a selected location in the patient. Included in the general definition of catheters are multiple tube devices. Multiple tube configurations typically include an outer tube, and an inner tube, where one of the tubes is moveable with respect to the other tube.

In this document, references to coordinates with respect to catheters or insertion devices will refer to axial or longitudinal locations and radial locations. Axial or longitudinal locations are typically locations with reference to an insertion axis. Radial locations will use the conventional 2-dimensional radial coordinates (r, θ) in a circle that is normal to the insertion axis. By combining an axial coordinate with the radial coordinates, a point can be located in three dimensional space relative to a given reference frame, such as the patient. Descriptions of the insertion axis in this document will generally refer to depth inside a patient along a line. It should be noted that although catheters need not be inserted along a straight line, a generally linear depth model will be used for ease of discussion. Also, the axial end, or tip of the catheter that is inserted into a patient is referred to herein as the distal end of the catheter, while the axial end of the catheter that remains toward the outside the patient is referred to as the proximal end.

In some medical procedures, it is desirable to distribute a media over a large target area within a patient. One procedure that utilizes a large distribution target area is neurosurgical cell therapy. Several prior approaches have been used to accomplish a large distribution target area. In one approach, a relatively small catheter, such as a single lumen catheter, is inserted into a patient several consecutive times. In this procedure, a measured amount of media, or dose, is delivered at one location, and then the catheter is withdrawn and re-inserted at a nearby location to deliver another dose. This process is repeated a number of times until the entire target area has received the desired dose. A problem with this approach

is that multiple insertions disturb a large amount of tissue in the patient. Each time that tissue is disturbed, there is a chance for tissue damage.

Some catheters utilize a single lumen host catheter that houses a delivery catheter having a deflected distal tip. The deflected distal tip exits the single lumen host catheter in a direction chosen by the orientation of the single lumen host catheter upon insertion. The deflected distal tip slightly increases the distribution of a single insertion and dose, however larger target area coverage is still needed. Steerable catheters exist, where the orientation and location of the distal tip can be changed while the distal tip is inserted in the patient, however, moving the distal tip while it is within the patient further disturbs tissue, which again, can lead to tissue damage. Also, steerable catheters are typically more complex and expensive to manufacture.

Another approach has been to insert a relatively large host catheter, the host catheter incorporating a number of internal passages for micro-catheters. The internal passages exit a distal end of the large host catheter at a distribution of locations around the distal end. Using this approach, the large host catheter is inserted in a center of the target area. Micro-catheters are then inserted in the various internal passages, and a dose is delivered at each of the distribution of locations. In this way a larger target area is covered without the need for multiple host catheter insertions. A problem with this approach is that the large host catheter displaces a large amount of tissue, even though the number of insertions is reduced.

What is needed is a device and method for distributing a media over a large target area. What is further needed is a device and method that disturbs a lower amount of tissue.

SUMMARY OF THE INVENTION

An insertion device is shown, the insertion device being adapted for delivery of a media inside a patient. The insertion device shown includes an insertion axis. One embodiment of the insertion device includes a first tube that is substantially coaxial with the insertion axis. Also included is a second tube substantially contained within the first tube, the second tube having a first range of motion with respect to the first tube. Also included is a third tube located at least partially within the second tube, the third tube having a second range of motion with respect to the first tube.

A method of introducing a media into a body cavity is shown, the method in one embodiment includes inserting an insertion device into the body cavity along an insertion axis. In this method, the insertion device includes a first tube that is substantially coaxial with the insertion axis, and a second tube substantially contained within the first tube the second tube having an angular range of motion with respect to the first tube. The insertion device in this method also includes a third tube at least partially within the second tube, the third tube having an axial range of motion with respect to the first tube. The method further includes rotating the second tube to a first position within the angular range of motion while the first tube remains stationary. The method includes advancing the third tube into the body cavity along the axial range of motion to a first location, and introducing the media to the first location through the third tube.

A method of manufacturing an insertion device is shown that includes forming a first tube with an axis that defines an insertion axis. The method also includes placing a second tube substantially contained within the first tube. The method also includes defining a first range of motion of the second tube with respect to the first tube; placing a third tube sub-

stantially contained within the second tube; and defining a second range of motion of the third tube with respect to the first tube.

A further method of introducing a media into a body cavity is shown that includes inserting an insertion device into the body cavity along an insertion axis. The insertion device in this method embodiment includes a first tube that is substantially coaxial with the insertion axis and a second tube substantially contained within the first tube, the second tube having an angular range of motion with respect to the first tube and an axial range of motion with respect to the first tube. The method includes rotating the second tube to a first position within the angular range of motion while the first tube remains stationary. The method further includes advancing the second tube into the body cavity along the axial range of motion to a first location, the first location being radially spaced at least partially radially outward from the insertion axis, and a radial component of the first location with respect to the insertion axis being determined by the first position within the angular range of motion. The method further includes introducing the media to the first location through the second tube.

An insertion device with an insertion axis is shown, the insertion device including an axial actuator that controls relative motion along the insertion axis. The insertion device further includes a first tube coupled to the axial actuator wherein the first tube is movable along the insertion axis in response to the axial actuator and a second tube having a radially biased distal end. In this embodiment, the second tube is substantially contained within the first tube in a first state. In this embodiment, the second tube is rotatable with respect to the first tube. In this embodiment, the second tube is axially movable to a second state, a portion of a distal end of the second tube being exposed from a distal end of the first tube in the second state.

A method of manufacturing an insertion device is shown, the method including defining an insertion axis and forming an axial actuator that controls relative motion along the insertion axis. The method also includes coupling a first tube to the axial actuator wherein the first tube is movable along the insertion axis in response to the axial actuator. The method also includes forming a second tube having a radially biased distal end. The method includes placing the second tube in a way that the second tube is substantially within the first tube in a first state; the second tube is rotatable with respect to the first tube; and the second tube is axially movable to a second state. In the second state, a portion of a distal end of the second tube is exposed from a distal end of the first tube.

A computer-readable medium is also shown with instructions stored thereon, the instructions when executed operable to cause location of a target volume in three dimensional space. The instructions, when executed, are also operable to cause plotting of a trajectory from an external point on a patient to the target volume and generation of a set of data corresponding to locations within the target volume. The set of data in one embodiment includes at least one axial position of a first tube along an insertion axis; at least one axial position of a second tube with respect to the first tube; and at least one rotational position of the second tube with respect to the first tube.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those skilled in the art that any arrangement which is calculated to achieve the same purpose may be substituted for the specific embodiment shown. This document is intended to cover any adaptations of variations of the present invention. It is to be understood that the above description is intended to be illustrative, and not

restrictive. The scope of the invention includes any other applications in which the above structures and fabrication methods are used. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1*a*. shows a top view of an embodiment of an insertion device.

FIG. 1*b*. shows a cross section of the insertion device from FIG. 1*a*.

FIG. 1*c*. shows a cross section of the insertion device from FIG. 1*a* in a further configuration.

FIG. 2*a* shows an isometric view of an embodiment of the insertion device in one configuration.

FIG. 2*b* shows an isometric view of an embodiment of the insertion device in another configuration.

FIG. 2*c* shows an isometric view of an embodiment of the insertion device in another configuration.

FIG. 3 shows an elevational view of a portion of an embodiment of an insertion device.

FIG. 4*a* shows an elevational view of another portion of an embodiment of an insertion device.

FIG. 4*b* shows a top view of the portion of the insertion device from FIG. 4*a*.

FIG. 5*a* shows an elevational view of another portion of an insertion device.

FIG. 5*b* shows a cross sectional view along line 5*b*-5*b* of the portion of the insertion device from FIG. 5*a*.

FIG. 6*a* shows a cross sectional view of an insertion device.

FIG. 6*b* shows an elevational view of the insertion device from FIG. 6*a*.

FIG. 6*c* shows a top view of the insertion device from FIG. 6*a*.

FIG. 7*a* shows an isometric view of a trajectory device.

FIG. 7*b* shows an additional isometric view of a trajectory device.

FIG. 8 shows a flowchart of a method for setting up a procedure according to one embodiment of the invention.

DETAILED DESCRIPTION

FIG. 1*a* shows a insertion device 100 according to one embodiment. The insertion device 100 in FIG. 1*a* is further shown in a sectional view as FIG. 1*b*, the section being taken along line 1*b*-1*b*.

The insertion device 100 includes a first tube 110, the first tube having a distal end 112 and a proximal end 114. Located on an upper surface of the proximal end 114 are a number of first indexing bumps 116. A central axis 102 is shown in FIG. 1*b*. The central axis 102 in this figure represents a central axis of the first tube. In one embodiment, the central axis 102 of the first tube is the same axis as an insertion axis of the insertion device 100.

The insertion device 100 further includes a second tube 130. The second tube 130 includes a distal end 132 and a proximal end 134. The proximal end 134 of the second tube 130 includes a knob portion 136, an indexing indicator 138 with a first index engaging recess 140, and a number of friction bumps 142. The proximal end 134 of the second tube 130 also includes a recess portion 144 that contains a number of second indexing bumps 146. The second tube 130 includes a first range of motion 148 with respect to the first tube 110 as shown by the arrows 148. In one embodiment, the friction bumps 142 interact with a surface of the first tube 110 to provide a designed level of resistance to rotation within the

first range of motion **148**. In one embodiment, a central axis of the second tube **130** is coaxial with the central axis **102**.

The first range of motion **148** is adjustable to select a radial direction, theta (θ). The second tube **130** is rotatable about the first range of motion **148** with respect to the first tube **110**. In one embodiment, the second range of motion is indexed by elements such as first indexing bumps **116**, which interact with the first index engaging recess **140** of the indexing indicator **138**. Non-indexed embodiments of the first range of motion are also contemplated within the scope of the invention. An indicating scale may also be included on the insertion device **100** to indicate the position of the third tube **150**, or second tube **130**, or both within the first range of motion **148**. In one embodiment, the indexing indicator **138** and its associated first index engaging recess **140** combine with the first indexing bumps **116** to serve as an indicator scale in addition to serving an indexing function.

The insertion device **100** further includes a third tube **150**. The third tube **150** includes a distal end **152** and a proximal end **154**. The distal end **152** of the third tube **150** includes a tip portion **156**, and a number of distribution holes **157**. In one embodiment, the tip portion **156** is blunt to protect tissue during insertion of the insertion device **100**. Along a sidewall of the third tube **150** is a second index engaging bump **158**. At the proximal end **154** of the third tube **150** is a connector **160**, which in one embodiment includes a luer hub configuration. The connector **160** is adapted for connection to a media source. The third tube **150** includes a second range of motion **162** with respect to the first tube **110** as shown by the arrows **162**. In one embodiment, a central axis of the third tube **150** is coaxial with the central axis **102**.

In one embodiment the third tube includes a coating (not shown) on an inner surface. The coating may include, but is not limited to a hydrophobic material, a hydrophilic material, or a biological agent. The biological agent may include a substance that promotes cell viability. In one embodiment where the media includes cells, the viability promoting biological coating helps to keep the cells alive for effective treatment at a target location within a patient.

FIGS. **1a** and **1b** illustrate the insertion device **100** in a configuration with the third tube **150** in a retracted state along the second range of motion **162**. In the retracted state along the second range of motion **162**, the second index engaging bump **158** is in an upper location within the number of second indexing bumps **146**. FIG. **1c** shows the insertion device **100** with the third tube **150** in an extended state along the second range of motion **162**. In the extended state along the second range of motion **162**, the second index engaging bump **158** is in a lower location within the number of second indexing bumps **146**.

Although only two positions of the third tube **150** in the second range of motion **162** are shown, any of a number of locations along the second range of motion **162** are possible. Although in one embodiment, a feature such as second indexing bumps **146** indexes the second range of motion **162**, non-indexed embodiments are also contemplated within the scope of the invention. An indicating scale may also be included on the insertion device **100** to indicate the position of the third tube **150** within the second range of motion **162**. One example would include a series of marks on the side of the third tube to indicate a position along the second range of motion.

The distal end **152** of the third tube **150** extends radially as well as axially in the extended state. A magnitude of radial extension in one embodiment is controlled by position of the third tube **150** along the second range of motion **162**. In one embodiment a magnitude of axial extension is also controlled

by position of the third tube **150** along the second range of motion **162**. In FIG. **1c**, a configuration of the distal end **152** of the third tube **150** controls both the axial and radial components of the extension of the distal end **152**.

In one embodiment, the distal end **152** extends in an arc. One skilled in the art will recognize that shapes other than an arc would also be within the scope of the invention. The radial extension component of the distal end **152** can be measured in part by an angle **162**. Angle **162** is defined as the internal angle between the central axis **102** and the distal end **152** of the third tube **150** as shown in FIG. **1c**. In one embodiment the arc at the distal end **152** of the third tube **150** is biased or molded permanently into the third tube. In one embodiment, the bias of the third tube is overcome by a stiffness of the second or first tube **6r** both when the third tube is in its retracted state as shown in FIGS. **1a** and **1b**. In one embodiment, the third tube **150** is therefore coaxial with the central axis **102** in the retracted state, while exhibiting a radial component outward from the central axis **102** in the extended state. Other embodiments that impart a radial component to the distal end **152** of the third tube **150** in an extended state are also contemplated within the scope of the invention. For example, the second tube could include a deflecting tip to impart a radial component to the distal end **152**.

In the extended state shown in FIG. **1c**, the number of distribution holes **157** are exposed from the distal end **132** of the second tube and the distal end **112** of the first tube. This allows distribution of a media such as cells in a region that is axially spaced and radially spaced from the distal ends of the first and second tubes.

In one embodiment, the tip portion **156** is visible to the use of an electronic imaging system. During a procedure such as neurosurgery, an electronic imaging system such as magnetic resonance imaging (MRI), or computed tomography (CT), radio wave imaging, or other imaging system may be used to image the patient. With the tip portion **156** of the third tube **150** of the insertion device **100** visible to the selected imaging technique, it is possible for the surgeon to see more accurately the placement of the distal end **152** of the third tube. This makes delivery of the selected media more accurate.

In one embodiment, the insertion device **100** may be adjusted in two ranges of motion. While the second range of motion selects magnitude of extension, the first range of motion **148** is adjustable to select a radial direction, theta (θ). The second tube **130** is rotatable about the first range of motion **148** with respect to the first tube **110**. In one embodiment, the second range of motion is indexed by elements such as first indexing bumps **116**, which interact with the first index engaging recess **140** of the indexing indicator **138**. Non-indexed embodiments of the first range of motion are also contemplated within the scope of the invention. An indicating scale may also be included on the insertion device **100** to indicate the position of the third tube **150**, or second tube **130**, or both within the first range of motion **148**. In one embodiment, the indexing indicator **138** and its associated first index engaging recess **140** combine with the first indexing bumps **116** to serve as an indicator scale in addition to serving an indexing function.

FIGS. **2a-2c** show an embodiment of a insertion device **200** in operation. The insertion device **200** is inserted into a patient **270** through an opening **271**. The insertion device **200** is inserted along an insertion axis **202** to a target location **280** within the patient. Upon insertion, the insertion device **200** is in a retracted state as shown in FIG. **2a**. Once the target location **280** is reached, an operator gripping a knob portion **236** and rotating a second tube **230** within a first tube **210**

makes a radial selection within a first range of motion **248**. In one embodiment, a third tube **250** also rotates with the second tube **230**.

As shown in FIG. *2b*, once the radial selection is made the third tube **250** is extended along a second range of motion **262**. Extension of the third tube reveals a distal end **252** of the third tube. The distal end **252** in this embodiment is biased in an arcuate shape, therefore directing the distal end **252** of the third tube **250** outward from the insertion axis **202** in a radial direction in addition to an axial direction. Extension of the distal end **252** along the second range of motion **262**, at the radial selection along the first range of motion **248**, directs the distal end **252** to a first location **272**. The extended distal end **252** of the third tube also exposes a number of distribution holes **257**. A media source that is connected to a connector **260** such as a luer hub is then actuated to dispense a media such as cells into the patient **270** adjacent to the first location **272**.

Because the distal end **252** of the third tube **250** is extended at least partially in a radial direction, rotation of the third tube **250** about the first range of motion **248** while the distal end **252** is extended could cause tissue damage. In one embodiment, the insertion device **200** includes a mechanism to prevent rotation about the first range of motion **248** while the distal tip **252** is extended. Rotation in the first range of motion **248** would be permitted once the distal end **252** is in a retracted position, and coaxial with the insertion axis **202**.

After the media has been delivered to the first location **272**, the third tube **250** is withdrawn back into the retracted state as shown in FIG. *2a*. This is accomplished by withdrawing the third tube **250** along the second range of motion **262**. The second tube is then rotated to a second radial selection within the first range of motion **248**. The third tube may then be re-extended to a second location **274** within the patient **270** as shown in FIG. *2c*. Once extended at the second location **274**, the number of distribution holes **257** are used to distribute media such as cells to an area adjacent the second location **274**.

The above detailed procedure of selection of direction, extension, distribution of media, and retraction can be repeated several times to fully cover a large area of distribution within a patient. Advantageously, the large area within the patient is covered with a single insertion of the insertion device **200**. The first tube **210** in this embodiment remains stationary, and does not rotate during the procedure, while elements such as other tubes substantially contained within the first tube **210** are allowed to rotate. Thus surrounding tissue is protected during rotation from damage due to friction between surrounding tissue and the first tube **210**, which is in direct contact with the surrounding tissue on a substantial portion of its side surfaces.

Although an infinite number of radial locations can be covered with this novel insertion device **200**, the first tube **210** in this embodiment need only be large enough to accommodate the second and third tubes **230** and **250**. The need for a large host catheter with a large number of internal passages for micro-catheters is thus eliminated. In one embodiment, when the distal end **252** of the third tube **250** is integrally molded with a bias, the need for complicated and expensive steerable catheters is also eliminated.

Indexing of the first and second ranges of motion **248** and **262** is advantageous because it allows the operator to easily adjust the various tubes of the insertion device within the first and second ranges of motion. A predetermined interval of adjustment is allocated for each index, and the operator need only adjust a number of indices for each iteration of extension/retraction as described above. In addition, the inclusion

of a visible indicator scale allows the operator to see exactly where in the ranges of motion the distal end **252** of the third tube **250** is located.

The inclusion of an electronically imageable tip **256** allows the operator to use the insertion device **200** in conjunction with an imaging system such as a magnetic resonance imaging (MRI) system, or similar imaging system. Features such as indexing, visible indicator scales, and imageable tips make locating and adjusting the insertion device **200** easier, more accurate, and safer for the patient **270**.

Components that are included in a further embodiment of an insertion device are shown in FIGS. *3-5b*. FIG. *3* shows a microcatheter **300**. The microcatheter **300** includes a proximal end portion **310** and a tube portion **330**. A fitting **340** is attached to one end of the proximal end portion **310**. The fitting is adapted for connection to additional devices, such as a media supply line, etc. In one embodiment, the fitting **340** includes a female luer lock fitting.

In one embodiment, a depth adjustment region **312** is included. In the embodiment shown in FIG. *3*, the depth adjustment region **312** includes a number of slots **314** at varying locations along a longitudinal axis of the proximal end portion **310**. One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize that alternative depth adjustment regions **312** are within the scope of the present disclosure, such as bumps, other notch profiles, or a smooth surface with a set screw, etc.

In one embodiment, an indicator scale **320** is included on the proximal end portion **310**. In the embodiment shown in FIG. *3*, the indicator scale **320** includes a number of marks **322** that are used to indicate a longitudinal position of the microcatheter **300** in relation to other elements of the insertion device. One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize that alternative indicator scales, including electronic position scales, etc. are within the scope of the present disclosure. In one embodiment, a rotational marker **318** is included on the proximal end portion **310**. The rotational marker **318** will be described in more detail in discussion of later figures. Further included in one embodiment, an index engaging feature **316** is attached to the proximal end portion **310**. The index engaging feature **316** will also be described in more detail in discussion of later figures.

FIGS. *4a* and *4b* show a cannula **400**. The cannula **400** includes a proximal end portion **410** and a tube portion **430**. In one embodiment, the proximal end portion **410** includes an inner diameter large enough to telescope with the proximal end portion **310** of the microcatheter **300**. In one embodiment, the tube portion **430** includes an inner diameter large enough to telescope with the tube portion **330** of the microcatheter **300**.

The cannula **400**, in one embodiment, includes an index housing **420** that includes a number of index slots **422** (FIG. *4b*). One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize that any of a number of indexing devices such as ratchet shaped teeth, bumps, etc. can also be used. Also included in one embodiment of the cannula **400**, is a depth adjustment actuator feature **412**. The depth adjustment actuator feature **412** will be discussed in more detail in discussion of later figures.

FIGS. *5a* and *5b* show an axial actuator **500**. The axial actuator includes a main body **510** and a stem portion **530**. Coupled to the stem portion **530** is a fitting **532** that is adapted for connection to additional devices that will be discussed in more detail in later figures.

In one embodiment, the main body **510** includes a first portion **514** and a second portion **524**. In the embodiment

shown in FIGS. 5a and 5b, the first portion is axially movable with respect to the second portion 524. The relative axial motion is controlled by a user control 520. In the embodiment shown, the user control 520 includes a thumb wheel. The user control 520 includes inner threads 522 that engage a number of outer threads 526 on the second portion 524. When the user control 520 is turned, the inner threads 522 drive the outer threads 526 and the second portion 524 axially with respect to the first portion 514. The first portion 514 may in this manner be moved axially with respect to the second portion along direction 516 either apart or together depending on the direction of rotation of the user control 520. One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize that alternate axial actuator mechanisms such as a ratchet, worm thread, etc. are possible within the scope of the present disclosure.

In one embodiment, the axial actuator 500 includes a fixing device 512, such as a set screw. The fixing device 512, in one embodiment, is used to secure the proximal end portion 410 of the cannula 400 within the first portion 514 of the main body 510. In this way, the cannula 400 is axially movable by adjusting the axial actuator 500 as described above.

FIG. 6a shows the elements from FIGS. 3-5b coupled together in one possible configuration of an insertion device 600. The proximal end portion 310 of the microcatheter 300 is located within the proximal end portion 410 of the cannula 400. The proximal end portion 410 of the cannula 400 is further located within the main body 510 of the axial actuator 500.

A depth adjustment actuator 610 is shown adjacent to the depth adjustment actuator feature 412 of the cannula 400. The depth adjustment actuator 610 includes an engagement feature 614 and a biasing device 612 in the embodiment shown. In one embodiment, the biasing device 612 includes an elastic O-ring that fits within the depth adjustment actuator feature 412. The biasing device 612 urges the engagement feature 614 into one of the slots 314 of the microcatheter 300. As discussed above, other depth adjustment designs are also contemplated within the scope of the invention.

The fixing device 512 is shown engaging the cannula 400 through a bushing 618. The bushing 618 is included on some embodiments to further fix a maximum depth of the insertion device 600 during initial setup of the insertion device 600 in a medical procedure.

In one embodiment, the microcatheter 300 is rotatable about the insertion axis 601, and the rotation is indexed. In the embodiment shown, the index engaging feature 316 of the microcatheter engages the number of index slots 422 of the cannula 400. Rotation of the microcatheter 300, is thus divided into discrete steps in embodiments that include the indexing feature.

The tube 330 of the microcatheter is shown passing along an insertion axis 601 of the insertion device 600. The microcatheter travels inside the tube 430 of the cannula 400 as both tubes 330 and 430 exit the insertion device 600 towards a distal end 602. The tubes 330 and 430 at their distal end 602 are the portions of the insertion device that are actually placed inside a patient for a procedure such as delivery of a media.

FIGS. 6b and 6c further show elements of the insertion device 600 from FIG. 6a. FIG. 6b shows the fitting 532 of the stem portion 530 attached to a portion of a trajectory device that will be discussed in later figures. FIG. 6c shows an indicator scale 620 that indicates a rotational position of the microcatheter 300 with respect to the cannula 400. A rotational range of motion of the microcatheter 300 with respect to the cannula 400 is shown by arrows 630. The indicator scale 620 includes a number of markings 622 that define exact

angles of position. The rotational marker 318 is coupled to the microcatheter 300, while the indicator scale 620 is coupled to the cannula 400. In this way, the relative position of the microcatheter 300 with respect to the cannula 400 is shown. One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize that alternative indicator scales, including electronic position scales, etc. are within the scope of the present disclosure.

FIG. 7a shows an embodiment of a trajectory guide 700. The trajectory guide 700 includes a stem portion 720. The stem portion further includes a fitting adaptor 724 such as a male luer lock, and a multi axis joint 722, such as a ball joint. The multi axis joint 722 allows adjustment of a trajectory axis 726. The trajectory guide 700 further includes a base 710 with at least one securing device 712 such as a screw.

In operation, the base 710 is attached to a patient using the securing devices 712. An example of a location on a patient includes mounting the base 710 directly to the skull of a patient. The stem 720 is then adjusted to point the trajectory axis 726 to a desired location within the patient. FIG. 7b further shows a fixing device 730 such as a lockring that is used to fix the trajectory axis 726 once targeting of the desired location is complete.

The trajectory guide 700 as shown in FIGS. 7a and 7b is used in one possible embodiment an insertion device from previous figures. For example, in FIG. 6b, the fitting 532 is shown secured to a stem such as found in the trajectory guide 700. Other embodiments do not include the trajectory guide 700, and use other means to adjust a trajectory before performing an insertion procedure.

In embodiments that include a trajectory guide 700, the axial actuator 500 is secured to the trajectory guide 700 with the insertion axis 601 substantially coaxial with the trajectory axis of the trajectory guide 700. A starting condition is set by adjusting a pair of variables. The microcatheter tube 330 is secured substantially within the cannula tube 430 using the depth adjustment actuator 610, and a desired slot 314. An axial starting depth of the two tubes 330 and 430 is then set by using the fixing device 512 to secure the cannula 400 to the axial actuator 500.

The insertion microcatheter tube 330 and the cannula tube 430 are inserted into a patient through an opening or incision. The microcatheter tube 330 and cannula tube 430 are inserted along the insertion axis 601 to a target location within the patient. Insertion is accomplished by actuation of the axial actuator 500 with the user control 520. During insertion, the microcatheter tube 330 is substantially contained within the cannula tube 430. Similar to previously described embodiments, the distal end of the microcatheter tube 330 may include a blunt tip to prevent tissue damage during insertion. Once the target location is reached, an operator makes a beginning radial selection using the indicator scale 620 shown in FIG. 6c. The microcatheter tube 330 is allowed to rotate substantially within the cannula tube 430 without rotation of the cannula tube 430. Tissue surrounding the cannula tube 430 is not subject to any rotational friction from side-walls of the cannula tube 430.

Once the radial selection is made, the microcatheter tube 330 is extended along the insertion axis 601 by itself, leaving the cannula tube 430 in place. This is accomplished by actuating the depth adjustment actuator 610, and moving to another selected slot 314. The depth of the microcatheter 330, as extended separate from the cannula tube 430, is indicated by the indicator scale 320. Again, very little tissue is disturbed due to the stationary position of the cannula tube 430.

Extension of the microcatheter tube 330 reveals a distal end of the microcatheter tube 330 with a bias as described in other

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embodiments above. The distal end in one embodiment is biased in an arcuate shape, therefore directing the distal end of the microcatheter tube **330** outward from the insertion axis **601** in a radial direction in addition to an axial direction.

Extension of the distal end of the microcatheter tube **330**, at the beginning radial selection, directs the distal end to a first location. The extended distal end of the microcatheter tube **330** also exposes a number of distribution holes as described in embodiments above. A media source that is connected to the fitting **340** such as a luer lock hub is then actuated to dispense a media such as cells into the patient adjacent to the first location.

Because the distal end of the microcatheter tube **330** is extended at least partially in a radial direction, rotation of the microcatheter tube **330** while the distal end is extended could cause tissue damage. In one embodiment, the insertion device **600** includes a mechanism such as a selectively keyed slot, etc. to prevent rotation while the distal tip of the microcatheter tube **330** is extended.

After the media has been delivered to the first location, the microcatheter tube **330** is withdrawn substantially within the cannula tube **430**. This is accomplished by using the depth adjustment actuator **610**, and moving to another selected slot **314**.

The microcatheter tube **330** is then rotated to a second radial selection using the indicator scale **620** shown in FIG. **6c**. The microcatheter tube **330** may then be re-extended to a second location within the patient. Once extended at the second location, the number of distribution holes are used to distribute media such as cells to an area adjacent the second location.

Several iterations of moving to a new radial selection and extending the microcatheter tube **330** can be performed to reach numerous locations within the patient. Advantageously, the cannula tube remains stationary during all iterations. One depth of the cannula tube **430** along the insertion axis **601** is described in the example above, however the iterations described above can be performed at multiple cannula tube **430** depths along the insertion axis **601** to accomplish a further distribution of media. Once the media has been delivered to the desired number of locations, the microcatheter tube **330** and the cannula tube **430** are withdrawn together by actuating the user control **520** of the axial actuator **500**.

Although the description of operation steps above is described in an order, other orders of operations are also possible within the scope of the invention. One of ordinary skill in the art, with the benefit of having read the present disclosure, will recognize alternative orders to accomplish the same objective.

FIG. **8** shows a flowchart for a method of operation of an insertion device as described in embodiments above. First the patient is imaged in three dimensions using any of a number of tissue imaging techniques such as MRI, CT, PET, etc. A target volume such as a tumor, or other target volume is then identified. Boundaries of the target volume are identified and marked using, for example, computer software that interfaces with the imaging device. A trajectory is then plotted to intersect with the target volume as identified. In one embodiment, the trajectory is plotted as a part of the imaging procedure. In one embodiment the trajectory is plotted as a part of the insertion procedure. In another embodiment, imaging, plotting the trajectory, and insertion are all performed in a single procedure. One method of plotting the trajectory includes imaging an actual trajectory of a trajectory guide such as the trajectory guide shown in FIGS. **7a** and **7b**, the trajectory guide being mounted directly to a patient.

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Using geometry, in conjunction with known values such as a starting tip location of a microcatheter, a starting tip location of a cannula, amount of bias or arc shape at a distal tip of the microcatheter, desired dose of media to be introduced, etc. a set of data can be generated for use in a procedure to introduce media to the target volume. In one embodiment, a table of instructions is generated that determines a number of steps in media delivery iterations.

By following the table of instructions for one iteration, or a number of iterations, a media concentration or concentration gradient can be effectively delivered over the target volume. A location of a distal tip of the microcatheter is determined by sets of data points in the table. For a larger target volume, a number of locations are determined by the table of instructions, and a dose of media is delivered at each of the locations. In this way a dose of media can be delivered to a large volume target area using a single insertion. In one embodiment, the table of instructions includes variables such as axial depth of the cannula, axial depth of the microcatheter, and rotational angle of the microcatheter.

CONCLUSION

Thus has been shown an insertion device and method of using and manufacturing a insertion device, wherein the insertion device is capable of distributing a media over a large distribution area inside a patient while reducing the amount of tissue disturbed by the procedure.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those skilled in the art that any arrangement which is calculated to achieve the same purpose may be substituted for the specific embodiment shown. This document is intended to cover any adaptations of variations of the present invention. It is to be understood that the above description is intended to be illustrative, and not restrictive. The scope of the invention includes any other applications in which the above structures and fabrication methods are used. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. An insertion device adapted for delivery of a media inside a patient, the insertion device having an insertion axis, comprising:

a first tube that is substantially coaxial with the insertion axis;

a second tube substantially contained within the first tube and axially fixed with respect to the first tube, the second tube having a first, rotational range of motion with respect to the first tube and being rotatable while maintaining a fixed axial position with respect to the first tube; and

a third tube located at least partially within the second tube, the third tube having a second, axial range of motion with respect to the first tube, the third tube including a tip portion formed with an arcuate shape to direct the third tube at least partially radially outward from the insertion axis when the tip portion is extended past a distal end of the first tube.

2. The insertion device of claim **1**, wherein the first range of motion is rotational substantially about the insertion axis.

3. The insertion device of claim **1**, wherein the second range of motion is axial substantially along the insertion axis.

4. The insertion device of claim **1**, wherein the tip portion is substantially coaxial with the first tube when the tip portion is within the first tube.

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5. The insertion device of claim 1, wherein the tip portion is integrally molded with the arcuate shape.

6. The insertion device of claim 1, wherein the third tube includes at least one radial hole in a sidewall region for delivering a media into a body cavity.

7. The insertion device of claim 1, wherein a distal end of the third tube is blunt to protect tissue during insertion.

8. The insertion device of claim 1, wherein the third tube includes a hydrophobic coating.

9. The insertion device of claim 1, wherein the third tube includes a hydrophilic coating.

10. The insertion device of claim 1, wherein the third tube includes a coating that contains a biological agent to promote viability of a biological media.

11. The insertion device of claim 1, wherein the third tube includes a portion that is visible to an electronic imaging technique.

12. The insertion device of claim 11, wherein the electronic imaging technique includes magnetic resonance imaging (MRI).

13. The insertion device of claim 11, wherein the electronic imaging technique includes radio wave imaging.

14. The insertion device of claim 1, further including a first indicator scale indicating the position of the second tube relative to the first tube within the first range of motion.

15. The insertion device of claim 1, further including a first indexing system that allows movement of the second tube relative to the first tube within the first range of motion at discrete increments.

16. The insertion device of claim 15, wherein the first indexing system includes at least a first index engaging recess and at least a friction bump.

17. The insertion device of claim 1, further including a second indicator scale indicating the position of the third tube relative to the second tube within the second range of motion.

18. The insertion device of claim 1, further including a second indexing system that allows movement of the third tube relative to the second tube within the second range of motion at discrete increments.

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19. The insertion device of claim 18, wherein the second indexing system includes at least a second index engaging bump and at least a second indexing bump.

20. An insertion device adapted for delivery of a media inside a patient, the insertion device having an insertion axis, comprising:

a first tube that is substantially coaxial with the insertion axis and having a first distal end and a first proximal end; a second tube substantially contained within the first tube and axially fixed with respect to the first tube, the second tube having a second distal end and a second proximal end and having a first rotational range of motion with respect to the first tube and being rotatable while maintaining a fixed axial position with respect to the first tube;

a third tube located at least partially within the second tube and having a third distal end and a third proximal end, the third tube having a second axial range of motion with respect to the first tube, the third tube including a tip portion at the third distal end formed with an arcuate shape to direct the third tube at least partially radially outward from the insertion axis when the tip portion is extended past a first distal end of the first tube;

a first indexing system that allows movement of the second tube relative to the first tube within the first rotational range of motion at discrete increments, the first indexing system formed at the first and second proximal ends of the first and second tubes; and

a second indexing system that allows movement of the third tube relative to the second tube within the second axial range of motion at discrete increments, the second indexing system formed at the second and third proximal ends of the second and third tubes.

21. The insertion device of claim 20, wherein the first indexing system includes a first indexing engaging recess and a plurality of first indexing bumps operable to engage the first index engaging recess to allow movement within the first rotational range of motion at discrete increments between the plurality of first indexing bumps.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,575,571 B2
APPLICATION NO. : 10/282584
DATED : August 18, 2009
INVENTOR(S) : Solar et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1456 days.

Signed and Sealed this

Seventh Day of September, 2010

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style.

David J. Kappos
Director of the United States Patent and Trademark Office